DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 8, 2015

3M Health Care
Matt S. Mortensen, Ph.D., RAC
Regulatory Affairs Specialist
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144

Re: K142034
Trade/Device Name: 3M Steri-Vac Sterilizer/Aerator Models GS5 and GS8
Regulation Number: 21 CFR 880.6860
Regulation Name: Sterilizer, Ethylene Oxide Gas
Regulatory Class: II
Product Code: FLF
Dated: December 8, 2014
Received: December 10, 2014

Dear Dr. Mortensen

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142034

Device Name
3M™ Steri-Vac™ Sterilizer/Aerator models GS5 and GS8

Indications for Use *(Describe)*
The 3M™ Steri-Vac™ Gas Sterilizer/Aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices in the following cycles:

Model	Cycle	Gas Expose Time (min.)	Temperature (deg C)	EO Concentration (mg/L)	Relative Humidity (%)*
GS5	Cool	270	38	736	40-80
	Warm	60	55	736	40-80
GS8	Cool	270	38	759	40-80
	Warm	60	55	759	40-80

Single or dual channel rigid and flexible scopes can be sterilized with non-lumened medical instruments in any of the GS sterilizer cycles provided the cycle parameters match the instrument's sterilization instructions. The load per cycle should not exceed 20 lumens.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification (510(k)) Summary

3M

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Matt S. Mortensen, Ph.D., RAC
Regulatory Affairs
Phone Number: (651) 737-2670
FAX Number: (651) 737-5320

Date of Summary: July 18, 2014

Device Name and Classification:

Common or Usual Name: EO Gas Sterilizer

Proprietary Name: 3M™ Steri-Vac™ Sterilizer/Aerator GS5 and GS8

Classification Name: Sterilizer, Ethylene-Oxide Gas (21 CFR § 880.6860)

Device Class: II

Product Code: FLF

Predicate Devices:

- K941748 – Steri-Vac™ 8XL EO Gas Sterilizer

Description of Device:

The 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 models are traditional ethylene oxide (EO) sterilizers that use 100% EO cartridges in a vacuum vessel. The sterilizers use fully automated controls for cycle processing and error handling.

Nonclinical Comparison to the Predicate Device

The 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers use the same principle of operation as the predicate device, a heated and humidified vessel inside of which a cartridge of 100% ethylene oxide gas is discharged. The cartridges of ethylene oxide used are identical to the predicate device. The sub-systems for heating, humidifying, introducing the gas, and safety

controls are modernized versions of the same sub-systems in the predicate device. 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers and the predicate device employ critical parameters (time, temp, gas concentration, and relative humidity) in the ranges specified by national and international standards and agency guidance documents.

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Indications for Use

The 3M™ Steri-Vac™ Gas Sterilizer/Aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices in the following cycles:

Model	***Cycle***	***Gas Expose Time (min.)***	***Temperature (°C)***	***EO Concentration (mg/L)***	***Relative Humidity (%)****
GS5	*Cool*	*270*	*38*	*736*	*40-80*
	Warm	*60*	*55*	*736*	*40-80*
GS8	*Cool*	*270*	*38*	*759*	*40-80*
	Warm	*60*	*55*	*759*	*40-80*

Single or dual channel rigid and flexible scopes can be sterilized with non-lumened medical instruments in any of the GS sterilizer cycles provided the cycle parameters match the instrument's sterilization instructions. The load per cycle should not exceed 20 lumens.

Comparison to Predicate Devices

Feature	**Submission Device**	**K941748 – Steri-Vac™ 8XL**
Intended Use	The 3M™ Steri-Vac™ Gas Sterilizer/Aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices. This gas sterilizer/aerator is intended for indoor use only.	Same
Designed for	EO sterilization in healthcare facilities	Same
EPA Registered Sterilant	YES, 100% EO Canisters Reg. No. 7182-1	Same
Chamber Size (W x H x D)	17" x 15" x 32.5" (GS5) 20" x 18" x 38" (GS8)	Same
Chamber Volume	4.8 cu. ft. (GS5) 7.9 cu. ft. (GS8)	7.9 cu. ft.
Chamber Material	6061-T6 aluminum	Same
Means of Heating	Electric heater blankets	Same

Means of Vacuum	Venturi effect using compressed air	Same
Process Monitoring and Control Devices	• Interactive touch panel with color display • Thermal Printer • Pressure gauge (analog) • Wall and chamber temp sensors • RH sensor • Pressure sensor	• LCD display w/keypad • Thermal printer • Pressure gauge (analog) • Wall and chamber temp sensors • RH sensor • Pressure sensor
Safety Devices	• Locking door • Automatic chamber test in every cycle • Vacuum-controlled gas cartridge puncture • Thermal cutouts • Automated error detection and recovery • Integral vent hood	Same
Temperature	55 ^{o}C / 38 ^{o}C	55 ^{o}C / 37 ^{o}C
Exposure Time	60 min. / 270 min.	60 min. / 180 min.
Nominal EO Concentration	736 mg/L (GS5); 759 mg/L (GS8)	759 mg/L (8XL)

Effectiveness

The effectiveness of the sterilization cycles included on the 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers is demonstrated by the application of testing and acceptance criteria described in the Recognized Consensus Standard:

・ *AAMI ST24:1999/(R) 2009 Third Edition; Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities,*

Summary of efficacy testing:

Empty Chamber Test – The sterilizer cycles were demonstrated in both models to provide complete inactivation of an AAMI challenge test pack in three consecutive sterilization runs.

Simulated Load Test – The sterilizer cycles were demonstrated in both models to provide complete inactivation of a load of AAMI challenge test packs representing 10% of the chamber volume in three consecutive sterilization runs.

Sterility Assurance Test – The sterilizer cycles were demonstrated in both models to provide complete inactivation of a load of AAMI challenge test packs representing 10% of the chamber volume in three consecutive sterilization runs which were run at half of normal gas exposure time. This test assures $>10^{6}$ sterility assurance level using the ISO 11135-1 "Overkill" approach.

The basis for effective inactivation of microbial spores is control over the critical physical parameters of exposure time, temperature, gas concentration and relative humidity. The performance of the sub-systems controlling these parameters meets the acceptance criteria when tested according to the prescribed methods in AAMI ST 24.

Summary of physical testing:

Chamber air temperature – All models were demonstrated to control the air temperature to set value +/- 3 degrees Celsius according to ST 24 Clause 5.1.5.1

Exposure time – All models were demonstrated to control exposure times to set value +/- 2% according to ST 24 Clause 5.1.5.2

Gas concentration – All models use a single-dose cartridge of 100% ethylene oxide where the entire contents are consumed in each cycle.

Relative humidity – All models were demonstrated to control relative humidity prior to gas exposure at a level ≥ 30% according to ST 24 Clause 5.1.5.3.

Safety

The 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers were tested for safety by Underwriters Laboratory to verify compliance to:

- *IEC 61010-1 (2001) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements,*
- *IEC 61010-2-010 (2003) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials,*
- *IEC 61010-2-040 (2005) First Edition; Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

In addition, 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers have been tested by a certified testing laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations (2009) for:
  - Radiated Emissions (FCC Part 15, Subpart B, Class A), and
  - Conducted Emissions (FCC Part 15, Subpart B, Class A)
- IEC 61326: *Electrical Equipment for Measurement, Control and Laboratory Use—EMC Requirements.*

Failure Hazards

Failure of the sterilizer can lead to delayed access to medical instruments, the potential for spread of infection, and the exposure of operators to ethylene oxide. When an error occurs, the system controller aborts the cycle, performs automated error recovery, and displays the error code(s).

To avoid hazardous situations, it is essential for users to follow all instructions provided by 3M and the manufacturers of the medical instruments which are being sterilized. The sterilizer must be installed and maintained according to the instructions provided. Operators of the sterilizer must be trained. Only supplies cleared for use in EO sterilization should be used in conjunction with the sterilizer. All applicable national and international standards and recommendations for ethylene oxide sterilization processes should be followed. Improper and incomplete cleaning has been specifically identified by industry and regulatory bodies as a major barrier to ultimately providing sterile medical instruments. Always follow instructions provided by the instrument manufacture for disassembling and cleaning.

User Information

3M provides users with installation manuals, operator manuals and other labeling describing appropriate use of the sterilizers, including information related to safety while working with ethylene oxide. In addition to labeling 3M provides users with in-person and online training, as well as technical assistance over the phone or in-person. Trained and certified service personnel located throughout the world are available for maintenance requests and other field support services.

Conclusion

The 3M Steri-Vac™ GS5 and 3M Steri-Vac™ GS8 sterilizers meet the performance standards of AAMI ST 24 and are substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.